

The listing of claims presented below replaces all prior versions and listings of claims in the application.

Listing of Claims

Claims 1-71 (Canceled)

72. (Currently amended) A drug delivery system ~~comprising~~ consisting of:
- a) a continuous hydrophobic gelled non-polymeric matrix, wherein the hydrophobic matrix is formed by gelling action of an emulsifier dissolved in an oily phase;
 - b) a discontinuous phase ~~comprising~~ consisting of a polymer dissolved in a water soluble organic solvent and
 - c) a biologically active agent dispersed within the discontinuous phase; ~~no aqueous phase is present in said drug delivery system, and~~ wherein said drug delivery system is in the form of gelled droplet in oil dispersion.
73. (Currently Amended) The drug delivery system of claim 72, wherein the gelled droplet in oil dispersion forms microparticles ~~are formed~~ in-situ, when the discontinuous phase comes in contact with any aqueous medium.
74. (Previously presented) The drug delivery system of claim 72, wherein the discontinuous phase, comprises a biodegradable polymer.
75. (Currently Amended) The drug delivery system of claim 74, wherein the biodegradable polymer is selected from the group consisting of polylactides, polyglycolides, polylactics, polylactic acid-co-glycolic acid, polylactide-co-glycolides, polyesteramides, star-branched polymers, polyphosphoesters, albumin, fibrin, fibrinogen combinations, polycaprolactones, polydioxanones, polycarbonates, polyhydroxybutyrates, polyalkylene oxalates, polyanhydrides, polyamides, polyurethanes, polyacetals, polyketals, polyorthocarbonates, polyphosphazenes, polyhydroxyvalerates, polyalkylene succinates,

poly(malic acid), poly(amino acids), chitin, chitosan, polyorthoesters, gelatin, collagen, polyethylene glycols, polyethylene oxides, polypropylene oxides, polyethers, betacyclodextrin, polysaccharides, polyvinyl alcohol, polyvinyl pyrrolidone, polyvinyl-alcohol, polyoxyethylene-polypropylene block copolymers; and copolymers, terpolymers and combinations ~~or~~ and mixtures thereof.

76. (Currently Amended) The drug delivery system of claim 72, wherein the discontinuous phase comprises a solvent ~~selected from a~~ for a polymer that is selected from the group consisting of N-methyl-2-pyrrolidone, N,N'-dimethylacetamide, water, 2-pyrrolidone, sorbitol, dimethyl sulfoxide, dimethylformamide, glycofural, glycerolformal, propylene glycol, polyethylene glycol, glycerol, caprolactam, decylmethyl sulfoxide, ethanol, dialkylamides, combinations and mixtures thereof.

77. (Previously presented) The drug delivery system of claim 72, wherein said non-polymeric hydrophobic gel matrix is prepared by the dissolution of the hydrophobic surfactant or emulsifier in the oily phase selected from the group consisting of animal oils, isopropyl myristate and vegetable oils or their fractionated counterparts or their salts with other acids.

78. (Currently Amended) The drug delivery system of claim 77, wherein said animal oil is selected from the group consisting of whale oil, shark liver oil ~~or~~ and mixtures thereof.

79. (Previously presented) The drug delivery system of claim 77, wherein said vegetable oil is selected from the group consisting of sesame seed oil, cottonseed oil, poppy seed oil, castor oil, coconut oil, canola oil, sun flower seed oil, peanut oil, corn oil, soyabean oil, capric-caprylic triglycerides and mixtures thereof.

80. (Currently Amended) The drug delivery system of claim 72, wherein said continuous hydrophobic gelled non-polymeric matrix comprises sorbitan esters ~~or~~ and mixtures thereof.

81. (Previously presented) The drug delivery system of claim 80, wherein said continuous

hydrophobic gelled non-polymeric matrix comprises sorbitan monostearate, sorbitan monopalmitate or mixtures thereof.

82. (Previously Presented) The drug delivery system of claim 72, wherein the biologically active agent is selected from the group consisting of peptide drugs, protein drugs, desensitizing agents, antigens, vaccines, anti-infectives, antibiotics, antimicrobials, antineoplastics, antitumor, antiallergenics, steroidal anti-inflammatory agents, analgesics, decongestants, miotics, anticholinergics, sympathomimetics, sedatives, hypnotics, antipsychotics, psychic energizers, tranquilizers, androgenic steroids, estrogens, progestational agents, humoral agents, prostaglandins, analgesics, antispasmodics, antimalarials, antihistamines, cardioactive agents, non-steroidal anti-inflammatory agents, antiparkinsonian agents, antihypertensive agents, beta-adrenergic blocking agents, nutritional agents, antivirals, DNA fragments, nucleic acids, RNA fragments, oligonucleotides, radioisotopes, or combinations of these classes of compounds or other forms such as uncharged molecules, molecular complexes, salts, ethers, esters, amides, and other chemically modified forms of the biologically active agent which are biologically activated when injected into a body.

83. (Currently Amended) The drug delivery system of claim 72, wherein the biologically active agent is selected from the group consisting of leuprolide acetate, goserelin acetate, octreotide acetate, paclitaxel, chlorpheniramine maleate, trimethoprim, sulfamethoxazole, ~~lactic acid~~, pseudoephedrine hydrochloride, olanzapine, captopril, lidocaine hydrochloride, felodipine, indomethacin, povidone iodine and terbutaline sulfate.

84. (Previously Presented) The drug delivery system of claim 73 wherein in-situ, represents an aqueous fluid in a site within, in or on a body.

85. (Currently Amended) The drug delivery system of claim 76, wherein the ~~concentration of the~~ polymer in said organic solvent in the polymer phase is present between 1-90%w/w.

86. (Currently Amended) The drug delivery system of claim 80 wherein the ~~concentration of said surfactant or emulsifier with respect to the polymer and organic solvent is between 5 and 50%w/w~~ continuous hydrophobic gelled non-polymeric matrix phase is present between 0.01-50%w/w.

87. (Previously presented) The drug delivery system of claim 72, wherein the microparticles formed in-situ, have a shape which is spherical, oblong, elliptical or irregular.

88. (Currently Amended) The drug delivery system of claim 87, wherein the ~~size of the microparticles is~~ have a size between 1 to 400 μ m.

89. (Previously presented) The drug delivery system of claim 87, wherein the ~~size of the microparticles is~~ have a size between 5 to 150 μ m.

90. (Previously presented) The drug delivery system of claim 88, wherein greater than 40-60% of the microparticles have a size of less than 100 μ m.

91. (Cancel)

92. (Cancel)

93. (Currently Amended) The ~~A~~ drug delivery system of claim 72, further comprising a ~~biologically active agent~~, a biologically inactive agent ~~or both~~.

94. (Cancel)

95. (Cancel)

96. (Currently amended) The drug delivery system of claim 72 wherein the ~~primary mechanism of release of the therapeutic~~ biologically active agent is mainly released by formation of polymeric microparticles and degradation of the polymer.

97. (Currently amended) The drug delivery system of claim 72 wherein the ~~secondary mechanism of release of the therapeutic~~ biologically active agent is additionally released by its dissolution into the oily continuous phase and then by further partitioning into an aqueous medium.

98. (Cancel).

99. (Previously Presented) The drug delivery system according to claim 72 further comprising a biologically active agent in the continuous phase.

100. (Withdrawn) A method for treating prostate cancer comprising administering to a subject in need thereof the drug delivery according to claim 83 wherein the biologically active agent is leuprolide acetate.

101. (Withdrawn) A method for treating breast cancer comprising administering to a subject in need thereof the drug delivery according to claim 83 wherein the biologically active agent is paclitaxel.

102. (Cancel)